

Applicant: Long, et al.
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Remarks/Arguments

Claims 20, 24 and 61 have been amended, Claims 1-19 and 43-60 have been cancelled without prejudice and new Claims 65-68 have been added. Accordingly, Claims 20-42 and 61-68 are currently pending.

I. Amendments:

Applicants thank Examiners Krishnan and Wilson for extending the courtesy of a telephone interview with Applicants' representative and Applicant Dale DeVore on February 2, 2005. Applicants have amended Claims 20 and 61, as discussed in the interview.

In that regard, Claims 20 and 61 have been amended to clarify that the eggshell membrane is obtained from mature fowl eggs. Support for these claims can be found throughout the specification and, more specifically, at pages 12-13, paragraphs 0055-0057, and at pages 16-17, paragraphs 0069-0070. No new matter has been added.

Claim 24 has been amended to be consistent with amended claim 20. Again, no new matter has been added.

New Claims 65 and 67 recite that the step of providing an eggshell membrane in the methods of claims 61 and 20, respectively, includes the steps of providing mature fowl eggs having an eggshell, egg yolk, egg white and eggshell membrane, in which the eggshell encases the egg yolk, egg white and eggshell membrane, and breaching the eggshell to expose the egg yolk, egg white and eggshell membrane. Support can be found at pages 12-13, paragraphs 0055-0057. No new matter has been added.

New Claims 66 and 68 recite that the step of providing an eggshell membrane in the methods of claims 61 and 20, respectively, includes the steps of providing cracked eggs having an eggshell and an eggshell membrane attached to the eggshell, and separating the eggshell membrane from the eggshell. Support can be found at pages 12-13, paragraphs 0055-0057. Again, no new matter has been added.

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II. The Invention:

The invention (claims 20-42, 67 and 68) is directed to methods for producing a hyaluronic acid (HA) composition which include the steps of: (1) providing eggshell membrane from a mature fowl egg and (2) extracting an HA rich fraction from the membrane.

In another aspect, the invention (claims 61-66) is directed to methods for producing a product for use with mammals which include the steps of: (1) providing eggshell membrane from a mature fowl egg, (2) extracting an HA rich fraction from the membrane and (3) incorporating the HA rich fraction in the product for use with mammals.

The cited prior art references do not disclose the methods for producing the HA composition from eggshell membrane or the methods for producing a product for use with mammals, as presently claimed.

III. Rejections:

A. Rejections based on 35 U.S.C. §102

1. Rejections based on Balazs

On pages 2-3 of the Office Action, Examiner Krishnan rejected Claims 1-11, 43-46, 61 and 62 under 35 U.S.C. §102(b) as being anticipated by Balazs (US 4,141,973).

As claims 1-11 and 43-46 have been cancelled, it is respectfully submitted that the rejections of these claims are now moot and should be withdrawn.

Regarding claims 61 and 62, Balazs is directed to an ultrapure hyaluronic acid (HA) and a method for producing same. Balazs teaches that the HA is obtained by extracting it from animal tissue, i.e., connective tissue such as rooster combs and human umbilical cords. See column 3, lines 22-28 and the examples at pages 10-11. Balazs further teaches that in order to provide a high concentration of HA which would avoid an inflammatory reaction

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when administered to an animal, extensive purification steps must be conducted. See examples at pages 10-15.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. V. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *4 Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913,1920 (Fed. Cir. 1989).

Nowhere does Balazs disclose a method which includes the step of extracting an HA rich fraction from eggshell membrane, as presently claimed (in claims 61 and 62).

Therefore, as Balazs does not disclose each and every element as set forth in the present claims and does not show the identical invention in as complete detail as claimed, it is respectfully submitted that Balazs cannot anticipate the present claims. See *Verdegaal*, 814 F.2d at 631 and *Richardson*, 868 F.2d at 1236.

Accordingly, it is respectfully requested that the rejections of Claims 1-11, 43-46, 61 and 62 under 35 U.S.C. §102(b), in view of Balazs, be withdrawn.

2. Rejections based on Henderson et al.

On pages 2-3 of the Office Action, Examiner Krishnan rejected Claims 12-16 and 50-60 under 35 U.S.C. §102(b) as being anticipated by Henderson et al. (US6,255,295).

As claims 12-16 and 50-60 have been cancelled, it is respectfully submitted that the rejections of these claims are now moot and should be withdrawn.

Accordingly, it is respectfully requested that the rejections of Claims 12-16 and 50-60 under 35 U.S.C. §102(b), in view of Henderson et al., be withdrawn.

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3. Rejections based on Osuji

On pages 2-3 of the Office Action, Examiner Krishnan rejected Claims 20-28 and 35-39 under 35 U.S.C. §102(b) as being anticipated by Osuji (*Biochimica et Biophysica Acta*, 1971, 244, 481-483).

Osuji is directed to the study of the acid glycosaminoglycan content of the membranes of shell free eggs taken from the oviduct of hens. The shell free eggs are clearly immature eggs that were obtained by sacrificing the hens. Osuji detected very low levels (i.e., less than 0.1 wt %) of HA in the membrane of the shell free eggs and failed to detect any other acid glycosaminoglycans in the membrane, such as chondroitin sulfate. The chondroitin sulfate was only found in the hen oviduct tissue itself and not in the membrane of the shell free eggs.

The shell free eggs studied by Osuji are immature eggs that have not yet formed an eggshell. See Osuji, second sentence of last paragraph on page 482 ("There is no reason to believe that the polyanion could be a contaminant from eggshell matrix as the latter had not been deposited at the time of collection [of the shell free eggs]"). As such, the membrane from shell free eggs (disclosed by Osuji) are clearly different from eggshell membrane (from mature eggs having an eggshell) as claimed. The fact that the membranes of the shell free eggs studied by Osuji contained no chondroitin sulfate clearly shows that they are different from the eggshell membranes as claimed. Nowhere does Osuji disclose a method that includes extracting an HA rich fraction from eggshell membrane. Moreover, nowhere does Osuji disclose any other material naturally found in eggshell membrane.

Therefore, as Osuji does not disclose each and every element as set forth in the present claims and does not show the identical invention in as complete detail as claimed, it is respectfully submitted that Osuji cannot anticipate the present claims. See *Verdegaal*, 814 F.2d at 631 and *Richardson*, 868 F.2d at 1236.

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Accordingly, it is respectfully requested that the rejections of Claims 20-28 and 35-39 under 35 U.S.C. §102(b), in view of Osuoji, be withdrawn.

4. Rejections based on Bracke

On pages 2-3 of the Office Action, Examiner Krishnan rejected Claims 29-31 under 35 U.S.C. §102(b) as being anticipated by Bracke et al. (US 4,517,295).

Bracke et al. is directed to HA prepared in high yield from streptococcus bacteria by fermenting the bacteria. Nowhere does Bracke et al. disclose a method which includes extracting an HA rich fraction from eggshell membrane.

Therefore, as Bracke et al. do not disclose each and every element as set forth in the present claims and do not show the identical invention in as complete detail as claimed, it is respectfully submitted that Bracke et al. cannot anticipate the present claims. See *Verdegaal*, 814 F.2d at 631 and *Richardson*, 868 F.2d at 1236.

Accordingly, it is respectfully requested that the rejections of Claims 29-31 under 35 U.S.C. §102(b), in view of Bracke, et al., be withdrawn.

5. Rejections based on Sakurai

On page 5 of the Office Action, Examiner Krishnan rejected Claims 32-34 under 35 U.S.C. §102(b) as being anticipated by Sakurai et al. (US 4,716,224).

Sakurai et al. is directed to a crosslinked HA prepared by crosslinking the HA or HA salt with a polyfunctional epoxy compound. Nowhere does Sakurai et al. disclose a method which includes the step of extracting an HA rich fraction from eggshell membrane.

Therefore, as Sakurai et al. do not disclose each and every element as set forth in the present claims and do not show the identical invention in as complete detail as claimed, it is respectfully submitted that Sakurai et al. cannot anticipate the present claims. See *Verdegaal*, 814 F.2d at 631 and *Richardson*, 868 F.2d at 1236.

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Accordingly, it is respectfully requested that the rejections of Claims 32-34 under 35 U.S.C. §102(b), in view of Sakurai et al., be withdrawn.

B. Rejections based on 35 U.S.C. §103

1. 35 U.S.C. §103 Rejections based on Henderson

On pages 3-4 of the Office Action, Examiner Krishnan rejected Claims 17-19 and 47-49 under 35 U.S.C. §103(a) as being obvious over Henderson (US 6,255,295).

As claims 17-19 and 47-49 have been cancelled, it is respectfully submitted that the rejections of these claims are now moot and should be withdrawn.

Accordingly, it is respectfully requested that the rejections of Claims 17-19 and 47-49 under 35 U.S.C. §103(a), in view of Henderson et al., be withdrawn.

2. Rejections based on Osuoji in combination with Baker

On pages 3-4 of the Office Action, Examiner Krishnan rejected Claims 40-42 under 35 U.S.C. §103(a) as being obvious over Osuoji, in combination with Baker et al. (*Biochemical Journal*, 1962, 82, 352-361).

As discussed above, Osuoji does not disclose extracting HA from eggshell membrane, as claimed. Instead, Osuoji merely identified very small quantities of HA in the membrane of shell free eggs, i.e. immature eggs taken from the oviduct of chickens.

Baker et al. is directed to the study of the organic material of hen's egg shell. Baker et al. reported that the eggshell itself contains chondroitin sulfate. Nowhere do Baker et al. disclose, teach or suggest a composition containing chondroitin sulfate naturally occurring in eggshell membrane.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the reference itself or in the

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knowledge generally available to one of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all claim limitations. See MPEP § 2142.

The teaching or suggestion to make the claimed combination (or modification) and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

The initial burden is on the examiner to provide some suggestion of the desirability of doing what the inventor has done. "To support the conclusion that the claimed invention is directed to obvious subject matter, the reference must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references. *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985).

Neither Osuoji nor Baker et al. teach or suggest extracting an HA rich fraction from eggshell membrane, let alone producing an HA composition containing both HA and at least one other naturally occurring material derived from eggshell membrane of the type and the amount specified in claims 40-42.

Accordingly, as neither Osuoji nor Baker et al. taken alone or combined teach or suggest all of the claim limitations of claims 40-42, a *prima facie* case of obviousness cannot be established.

Therefore, it is respectfully requested that the rejections of Claims 40-42 under 35 U.S.C. §103(a), in view of Osuoji in combination with Baker et al., be withdrawn.

3. Rejections based on Balazs in combination with Henderson

On page 9 of the Office Action, Examiner Krishnan rejected Claims 61, 63 and 64 under 35 U.S.C. §103(a) as being unpatentable over Balazs (US 4,141,973) in combination with Henderson et al. (US 6,255,295).

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As discussed more fully above, Balazs does not teach or suggest a method which includes extracting an HA rich fraction from eggshell membrane (claim 61) or an HA rich fraction that also includes at least one other naturally occurring constituent of the eggshell membrane (as specified in claim 63).

Henderson et al. is directed to a composition for the protection, treatment and repair and for reducing inflammation of connective tissue in mammals by administering the composition to the mammal. The composition includes a combination of at least two compounds that can include hyaluronic acid (HA) and glucosamine. However, similar to Balazs, nowhere do Henderson et al. disclose extracting an HA rich fraction from eggshell membrane (claim 61) or an HA rich fraction that also includes at least one other naturally occurring constituent of the eggshell membrane (as specified in claim 63).

Accordingly, neither Balazs nor Henderson et al. taken alone or combined teach or suggest all of the claim limitations of claims 61, 63 and 64. Moreover, Balazs actually teaches away by teaching that the HA composition is extracted from animal tissue.

Therefore, it is respectfully requested that the rejections of Claims 61, 63 and 64 under 35 U.S.C. §103(a), in view of Balazs in combination with Henderson et al., be withdrawn.

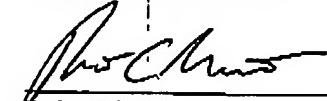
CONCLUSION

Applicants respectfully submit that the application as amended, including claims 20-42 and 61-68, is now in proper form for allowance, which action is earnestly solicited. If resolution of any remaining issue is required prior to examination of the application, it is

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respectfully requested that the Examiner contact Applicants' undersigned attorney at the telephone number provided below.

Respectfully submitted,



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